IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., and VELOXIS PHARMACEUTICALS A/S,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
MYLAN INC. and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Santarus, Inc. and Veloxis Pharmaceuticals A/S (collectively, "Plaintiffs"), for their Complaint against Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Defendants"), hereby allege as follows:

PARTIES

1. Plaintiff Santarus Inc. ("Santarus") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3611 Valley Centre Drive, Suite 400, San Diego, CA 92130.

2. Plaintiff Veloxis Pharmaceuticals A/S ("Veloxis") is a Danish corporation having a principal place of business at Bøge Alle 5, 2th, DK-2970, Horsholm, Denmark.

3. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma") is a West Virginia corporation, and a wholly-owned subsidiary and agent of Defendant Mylan Inc., having a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information and belief Defendant Mylan Pharma manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial

district. Mylan Pharma is qualified to do business in Delaware and has appointed a registered agent for service of process.

4. Upon information and belief, Defendant Mylan Inc. ("Mylan Inc.") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317. Upon information and belief, Defendant Mylan Inc., itself and through its wholly-owned subsidiary and agent Defendant Mylan Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of U.S. Patent Nos. 7,658,944 ("the '944 patent") and 8,124,125 ("the '125 patent") (attached as Exhibits A and B). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, Defendants are in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Mylan Inc. conducts its North American operations, in part, through Mylan Pharma and together, they collaborate in developing, manufacturing, marketing, and selling generic drugs throughout the United States, including in this judicial district.

8. This Court has personal jurisdiction over Mylan Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware and because it has appointed a registered agent for service of process in Delaware.

9. This Court has personal jurisdiction over Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its wholly-owned subsidiary and agent, Mylan Pharma, a corporation with a registered agent for service of process in Delaware.

10. This Court also has personal jurisdiction over each Defendant by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Santarus, a Delaware corporation.

11. Defendants have previously submitted to the jurisdiction of this Court. Mylan Pharma has, *inter alia*, initiated suit and asserted claims arising under the Patent Laws of the United States in this Court. *See, e.g.*, *Mylan Pharmaceuticals Inc. v. Ethypharm S.A.*, C.A. No. 10-1064-LPS and *Mylan Pharmaceuticals Inc. v. Galderma Laboratories, Inc.*, C.A. No. 10-892-LPS. Defendants have also previously availed themselves of this Court by asserting counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this jurisdiction. *See, e.g.*, *Forest Laboratories, Inc. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 08-52-GMS; *Shionogi Pharma, Inc. v. Mylan Inc.*, C.A. No. 10-135-RBK; and *Shionogi Pharma, Inc. v. Mylan Inc.*, C.A. No. 10-1077-RGA.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

THE PATENTS-IN-SUIT

13. On February 9, 2010, the '944 patent, titled "Solid Dosage Form Comprising a Fibrate," was duly and legally issued by the United States Patent and Trademark Office. Veloxis is the owner of the '944 patent.

14. On February 28, 2012, the ’125 patent, titled “Solid Dosage Form Comprising a Fibrate,” was duly and legally issued by the United States Patent and Trademark Office. Veloxis is the owner of the ’125 patent.

15. Santarus was granted the exclusive, royalty-bearing license under the ’944 and ’125 patents to market, import, use, sell, offer for sale, and otherwise commercialize certain pharmaceutical products, including FENOGLIDE®, in the United States. Santarus has the rights to enforce the ’944 and ’125 patents, including the right to sue for infringement of those patents.

16. Santarus holds New Drug Application (“NDA”) No. 22-118 for 40 mg and 120 mg fenofibrate orally disintegrating tablets. Santarus markets these tablets in the United States under the trade name FENOGLIDE®. The ’944 and ’125 patents are listed in the U.S. Food and Drug Administration’s (“FDA”) Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) with respect to FENOGLIDE®.

ACTS GIVING RISE TO THIS ACTION
COUNT I – PATENT INFRINGEMENT – ’944 PATENT

17. Plaintiffs reallege Paragraphs 1-16 as if fully set forth herein.

18. Upon information and belief, Mylan Pharma, on behalf of itself and as the agent of Mylan, Inc., submitted ANDA No. 20-4475 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA approval for the commercial manufacture, use, and sale of generic 40 mg and 120 mg fenofibrate orally disintegrating tablets (named “Fenofibrate Tablets”) prior to the expiration of the ’944 patent.

19. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Mylan Pharma certified that the claims of the ’944 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Fenofibrate Tablets. Mylan Pharma provided written notification of ANDA No. 20-4475 and its

§ 505(j)(2)(A)(vii)(IV) certification by sending Plaintiffs a letter bearing a date of December 18, 2012.

20. Mylan Pharma's submission of ANDA No. 20-4475 to the FDA constitutes the infringement of the '944 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports any Fenofibrate Tablets, or induces or contributes to any such conduct, it would further infringe the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

21. Mylan Inc. is jointly and severally liable for Mylan Pharma's infringement of the '944 patent. Upon information and belief, Mylan Inc. participated in, contributed to, aided, abetted, and/or induced Mylan Pharma's submission of ANDA No. 20-4475 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA.

22. Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 20-4475 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA constitute infringement of the '944 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports any Fenofibrate Tablets, or induces or contributes to any such conduct, it would further infringe the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

23. Upon information and belief, Defendants were aware of the existence of the '944 patent prior to filing ANDA No. 20-4475.

24. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law. The balance of hardships as between Plaintiffs and Defendants, and the public interest, further support the Court enjoining Defendants' infringing activities.

COUNT II – DECLARATORY JUDGMENT – '944 PATENT

25. Plaintiffs reallege Paragraphs 1-24 as if fully set forth herein.

26. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), (b), and (c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

27. On information and belief, Defendants filed or caused to be filed with the FDA ANDA No. 20-4475 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Defendants' Fenofibrate Tablets in the United States before the expiration of the '944 patent.

28. On information and belief, Defendants have knowledge of the '944 patent and have filed ANDA No. 20-4475 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Fenofibrate Tablets in the United States. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Fenofibrate Tablets in accordance with the indications sought by Defendants, and will therefore infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), or (c).

29. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '944 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

COUNT III – PATENT INFRINGEMENT – '125 PATENT

30. Plaintiffs reallege Paragraphs 1-29 as if fully set forth herein.

31. Upon information and belief, Mylan Pharma, on behalf of itself and as the agent of Mylan, Inc., submitted ANDA No. 20-4475 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA approval for the commercial manufacture, use, and sale of generic 40 mg and 120 mg fenofibrate orally disintegrating tablets (named "Fenofibrate Tablets") prior to the expiration of the '125 patent.

32. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Mylan Pharma certified that the claims of the '125 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Fenofibrate Tablets. Mylan Pharma provided written notification of ANDA No. 20-4475 and its § 505(j)(2)(A)(vii)(IV) certification by sending Plaintiffs a letter bearing a date of December 18, 2012.

33. Mylan Pharma's submission of ANDA No. 20-4475 to the FDA constitutes the infringement of the '125 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports any Fenofibrate Tablets, or induces or contributes to any such conduct, it would further infringe the '125 patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. Mylan Inc. is jointly and severally liable for Mylan Pharma's infringement of the '125 patent. Upon information and belief, Mylan Inc. participated in, contributed to, aided, abetted, and/or induced Mylan Pharma's submission of ANDA No. 20-4475 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA.

35. Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 20-4475 and its § 505(j)(2)(A)(vii)(IV) certification to the FDA constitute infringement of the '125 patent under 35 U.S.C. § 271(e)(2)(A).

Moreover, if Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports any Fenofibrate Tablets, or induces or contributes to any such conduct, it would further infringe the '125 patent under 35 U.S.C. § 271(a), (b), and/or (c).

36. Upon information and belief, Defendants were aware of the existence of the '125 patent prior to filing ANDA No. 20-4475.

37. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law. The balance of hardships as between Plaintiffs and Defendants, and the public interest, further support the Court enjoining Defendants' infringing activities.

COUNT IV – DECLARATORY JUDGMENT – '125 PATENT

38. Plaintiffs reallege Paragraphs 1-37 as if fully set forth herein.

39. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), (b), and (c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

40. On information and belief, Defendants filed or caused to be filed with the FDA ANDA No. 20-4475 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Defendants' Fenofibrate Tablets in the United States before the expiration of the '125 patent.

41. On information and belief, Defendants have knowledge of the '125 patent and have filed ANDA No. 20-4475 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Fenofibrate Tablets in the United States. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Fenofibrate Tablets in accordance with the indications sought by Defendants,

and will therefore infringe, either literally or under the doctrine of equivalents, one or more claims of the ’125 patent under 35 U.S.C. § 271(a), (b), or (c).

42. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the ’125 patent. Defendants’ actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Santarus and Veloxis pray for judgment in its favor as follows:

a) declare that United States Patent Nos. 7,658,944 and 8,124,125 are valid and enforceable;

b) declaring that, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed the ’944 and ’125 patents by submitting ANDA No. 20-4475 to the FDA seeking to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Defendants’ Fenofibrate Tablets prior to the expiration of the ’944 or ’125 patents;

c) declaring that Defendants’ commercial manufacture, use, offer for sale, sale in, or importation into the United States of Defendants’ Fenofibrate Tablets prior to the expiration of the ’944 or ’125 patents would constitute infringement of said patents under 35 U.S.C. § 271(a), (b), and/or (c) as set forth above and in violation of Plaintiffs’ patent rights;

d) ordering that the effective date of any FDA approval of Defendants’ Fenofibrate Tablets shall be no earlier than the expiration date of the ’944 and ’125 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoining Defendants, and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining approval of ANDA No. 20-4475 until the expiration of the '944 or '125 patents;

f) enjoining Defendants, and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Defendants' Fenofibrate Tablets within the United States, or importing Defendants' Fenofibrate Tablets into the United States, prior to the expiration of the '944 and '125 patents, in accordance with 35 U.S.C. § 271(e)(4)(B); and

g) granting Plaintiffs such further and additional relief that this Court deems just and proper.

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January 28, 2013